

DOCKET NO.: C1039.70083US05

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Arthur M. Krieg et al.

Serial No:

10/789,536

Confirmation No:

9640

Filed:

February 26, 2004

For:

IMMUNOMODULATORY OLIGONUCLEOTIDES

Examiner:

Nita M. Minnifield

Art Unit:

1645

# CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 7th day of July, 2005.

Helen C. Lockhart, Ph.D., Reg. No. 39,248

### MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

# STATEMENT FILED PURSUANT TO THE DUTY OF DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

## Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement is being resubmitted at the request of Examiner Minnifield in the Office Action dated February 10, 2005. The initial Information Disclosure Statement had been submitted on February 26, 2004 prior to the issuance of a first Office Action for the above referenced application. No fee or certification is believed to be due. If there is a fee due, the balance may be charged to Deposit Account 23/2825.

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### Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

### Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

- 1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
- 2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
- 3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

Serial No.: 10/789,536

Docket No. C1039.70083US05

Date: July 7, 2005

X07/10/05X

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An early and favorable action is hereby requested.

Respectfully submitted,

By:

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FORM PTO-1449/A and B (Modified)	APPLICATION NO.:	10/789,536	ATTY. DOCKET NO.: C1039.70083US05	
INFORMATION DISCLOSURE	FILING DATE:	February 26. 2004	CONFIRMATION NO.: 9640	
STATEMENT BY APPLICANT	APPLICANT:	Arthur M. Krieg et al.		
Sheet 1 1 2005 67 2	GROUP ART UNIT:	1645	EXAMINER: Nita M. Minniefield	

RADEMARY	•	U.S. P.	ATENT DOCUMENTS	
Cite	U.S. Patent Doc	ument	Name of Patentee or Applicant of Cited	Date of Publication or of issue of Cited Document MM-DD-YYYY
No.	Number	Kind Code	Document	
		No.	No. Number Kind	No. Number Kind Document

FOREIGN PATENT DOCUMENTS

Lixaminer 5	Cite	Foreign Patent Document		ent	Name of Patentee or Applicant of Cited	Date of Publication of	Translation
	No.	Office/ Country	Number	Kind Code	Document (not necessary)	Cited Document MM-DD-YYYY	(Y/N)
	B1	EPO	0 178 267 A2			04-16-1986	
	B2	JР	62-148428			07-02-1987	
	B3	PCT	US91/05815			08-14-1991	
	B4	PCT	US91/01327			09-05-1991	
	B5	PCT	0 216 133 B1			07-28-1993	
	В6	PCT	US94/02471			03-07-1994	
	B7	EP	0 302 758 B1			03-16-1994	
	B8	PCT	WO95/26204			10-1995	
	B9	PCT	WO96/02555		<del></del>	02-01-1996	

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's	Cite	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item	Translation
Initials	No	(book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	(Y/N)
	C1	Anfossi et al. (P.N.A.S., 86, 9, 3379-83, 89, HCAPLUS, AN 1989:475562)	
	C2	Azad, Raana F. et al., "Antiviral Activity of a Phosphorothioate Oligonucleotide Complementary to	
		RNA of the Human Cytomegalovirus Major Immediate-Early Region," Antimicrobial Agents and Chemotherapy, (1993) 37: 1945-1954.	
	C3	Azuma, I., "Biochemical and Immunological Studies on Cellular Components of Tubercle Bacilli," Kekkaku (1992) 67(9):45-55.	
	C4	Blaxter et al., "Genes expressed in Brugia malayi infective third stage larvae," Molecular and Biochemical Parasitology, (1996) 77:77-93.	
	C5	Etchart et al. "Class I-restricted CTL induction by mucosal immunization with naked DNA encoding measles virus haemagglutinin" pp. 15775761 vol 72, 1998	
	C6	Etlinger, "Carrier Sequence Selection One Key to Successful Vaccines," <i>Immunology Today</i> , (1992) 13(2):52-55	
	C7	Fox, R.I., "Mechanism of Action of Hydroxychloroquine as an antirheumatic Drug," Chemical Abstracts (1994) 120:15, Abstract No. 182630	
	C8	Kataoka T, et al., "Antitumor Activity of Synthetic Oligonucleotides with Sequences from cDNA Encoding Proteins of Mycobacterium bovis BCG," Jpn. J. Cancer Res (1992) 83:244-247.	
	C9	Kimura Y, et al., "Binding of Oligoguanylate to Scavenger Receptors Is Required for Oligonucleotides to Augment NK Cell Activity and Induce IFN," J. Biochem (1994) 116(5):991-994	
	C10	Kuramoto et al., "Oligonucleotide Sequences Required for Natural Killer Cell Activation," <i>Jpn. J. Cancer Res.</i> , (1992) 83:1128-1131.	

FORM PTO-1449/A and B (Modified)			APPLICATION NO.:	10/789,536	ATTY. DOCKET NO.: C1039.70083US05	
i	RMATION D			FILING DATE:	February 26, 2004	CONFIRMATION NO.: 9640
STATEMENT BY APPLICANT		APPLICANT:	Arthur M. Krieg et al.			
Sheet	2	of	2	GROUP ART UNIT:	1645	EXAMINER: Nita M. Minnifield
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	<del></del>	OTHER ART — NON PATENT LITERATURE DOCUMENTS	I
Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C11	Messina et al., "The Influence of DNA Structure on the <i>in vitro</i> Stimulation of Murine Lymphocytes by Natural and Synthetic Polynucleotide Antigens," <i>Cellular Immunology</i> (1993) 147:148-157.	
	C12	Messina et al., "Stimulation of <i>in vitro</i> Murine Lymphocyte Proliferation by Bacterial DNA," <i>The Journal of Immunology</i> (1991) 147(6):1759-1764.	
	C13	Mottram, et al., "a Novel CDC2-Related Protein Kinase From Leishania Mexicana.LmmCRK1. Is Post- Translationally Regulated During the Life Cycle", <i>J. Biol. Chem.</i> , 268(28):21044-21052 (1993)	
	C14	Ren jun et al. (Zhonghua Zhong Zazhi, 1994, 16, 4, 247-50, HCAPLUS, AN 1995: 198874)	
	C15	Sato et al., "Immunostimulatory DNA Sequences Necessary for Effective Intradermal Gene Immunization," <i>Science</i> (1996) 273:352-354.	
	C16	Schnell et al., "Identification and Characterization of a Saccharomyces Cerevisiae Gene (PAR1) Conferring Resistance to Iron Chelators," Eur. J. Biochem. (1991) 200:487-493.	
	C17	Stull et al., "Antigene, Ribozyme and Aptamer Nucleic Acid Drugs: Progress and Prospects," <i>Pharmaceutical Research</i> , (1995) 12(4):465-483.	
	C18	Tanaka T. et al., "An Antisense Oligonucleotide Complementary to a Sequence in IG2b Germline Transcripts, Stimulates B Cell DNA Synthesis, and Inhibits Immunoglobulin Secretion, <i>J. Exp. Med.</i> , (1992) 175:597-607.	
	C19	Tokunaga T. et al., "Synthetic Oligonucleotides with Particular Base Sequences from the cDNA Encoding Proteins of <i>Mycobacterium bovis</i> BCG Induce Interferons and Activate Natural Killer Cells," <i>Microbiol. Immunol.</i> (1992) 36(1):55-66.	
	C20	Tokunaga, "A synthetic Single-stranded DNA, Poly(dG,dC), Induces Interferon-alpha/beta and gamma, Augments Natural Killer Activity, and Suppresses Tumor Growth," <i>Jpn. J. Cancer Res.</i> (1988) 79(6):682-686.	
	C21	Wallace et al., "Oligonucleotide Probes for the Screening of Recombinant DNA Libraries,," <i>Methods in Enzymology</i> , (1987) 152:432-442.	
	C22	Whalen R., "DNA Vaccines for Emerging Infectious Disease: What If?," Emerging Infectious Disease, (1996) 2(3):168-175.	
	C23	Wu G.Y. et al., "Receptor-mediated Gene Delivery and Expression in vivo," J. Biological Chemistry, (1988) 263:14621-14624.	
	C24	Yamamoto S. et al., "DNA from Bacteria, but not from Vertebrates, Induces Interferons, Activates Natural Killer Cells and Inhibits Tumor Growth," <i>Microbiol. Immunol.</i> (1992) 36(9):983-997.	

EXAMINER	DATE CONSIDERED

<sup>#</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>\*</sup> copies of these patents and patent applications are not enclosed pursuant to the waiver by the USPTO of the requirement under 37 C.F.R. 1.98 (a)(2)(i) for patent applications filed after June 30, 2003.